OCT 1 5 2008

510(k) SUMMARY

This summary of 510 (k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510 (k) number is: K080632

Applicant information:

Initial Date Prepared:	29 February 2008
Name:	Clearlab SG Pte Ltd
Address:	139, Joo Seng Road Singapore 368362
Contact Person/ Official Correspondent:	Tan Hwee Ee
Phone number:	(65)-63801-347
Fax number:	(65)-6282 3953
FDA US Agent/ Contact Person:	Medvice Consulting, Inc. Martin Dalsing
Phone number:	(970) 243-5490
Fax number:	(970) 243-5501

Device Information:

Device Classification:	Class II
Classification number:	LPL
Classification name:	Lenses, Soft Contact, Daily Disposable
Trade name:	Clear1-day® (hioxifilcon A) Daily Disposable Soft Contact Lens

Equivalent Predicate Devices:

The Clear1-day® (hioxifilcon A) Daily Disposable Soft Contact Lenses are substantially equivalent to the following predicate devices:

1. Extreme H_2O (hioxifilcon A), K992692, Manufactured by Hydrogel Vision Corp.
2. Clear All Day (hioxifilcon A), K052290, Manufactured by Clearlab SG Pte Ltd.

Device Description:

The Clear1-day® (hioxifilcon A) Daily Disposable Soft Contact Lens is available as a single vision spherical lens. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

The non-ionic lens material, (hioxifilcon A) is a ultra high molecular weight random copolymer of 2-hydroxyethyl methacrylate (2-HEMA) and 2,3-Dihydroxpropyl Methacrylate (Glycerol Methacrylate, GMA) cross-linked with ethylene glycol dimethacrylate. It consists of 42% hioxifilcon A and 58% water by weight when immersed in a buffered saline solution. The lens is available with a pale blue visibility-handling tint, color additive 'Reactive Blue # 4', 21 CFR part 73.3121. The United States Adopted Names Council (USAN) has adopted the (hioxifilcon A) name.

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a colorless, transparent optical surface. The hydrophilic properties of the lens require that it be maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat warped however, it will return to its proper configuration when completely rehydrated in the proper storage solution.

The hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 58% water by weight. The physical properties of the lens are:

Refractive Index at 21°C:	**1.4011**(wet)
Light Transmission:	**> 95%**
Surface Character:	**Hydrophilic**
Water Content at 21°C:	**59.77 %**
Specific Gravity at 21°C:	**1.086**(wet)
Oxygen Permeability at 34-36°C:	**25.38 x 10^{-11}**(cm^2/sec) (ml O_2/ml x mm Hg), (revised Fatt method).

Intended Use:

The Clear1-day® (hioxifilcon A) Daily Disposable Soft Contact Lens is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.

The lens is intended to be worn once and then discarded at the end of each wearing period on a daily basis. The patient should be instructed to start the next wearing period with a new lens.

Technological Characteristics:

The technological characteristics of the Clear1-day® (hioxifilcon A) Daily Disposable Soft Contact Lens as compared to the technological characteristics of the predicate devices are illustrated in the following table.

Pre-Clinical equivalency /Device	Clear1-day® (hioxifilcon A) New Device	Clear All Day (hioxifilcon A) Predicate Device	Extreme H_2O (hioxifilcon A) Predicate Device
Intended Use	Indicated for daily wear for the correction of visual acuity in non-aphakic persons with non-diseased eyes with myopia or hyperopia.	Indicated for daily wear for the correction of visual acuity in aphakic and non-aphakic persons with non-diseased eyes with myopia or hyperopia.	Indicated for daily wear for the correction of visual acuity in aphakic and non-aphakic persons with non-diseased eyes with myopia or hyperopia.
Functionality	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.
Indications	Daily Disposable, Soft (hydrophilic) contact lens	Daily Wear, Soft (hydrophilic) contact lens	Daily Wear, Soft (hydrophilic) contact lens
Production Method	Spun-Cast	Cast-molded	Cast-molded
FDA Group #	Group #2 >50% Water, non-ionic Polymer	Group #2 >50% Water, non-ionic Polymer	Group #2 >50% Water, non-ionic Polymer
USAN name	Hioxifilcon A	Hioxifilcon A	Hioxifilcon A
Water Uptake (%)	59.77%	56.47%	60.24%
Oxygen Permeability (Dk)	25.38×10^{-11} (cm2/sec) (ml O2/ml x mm Hg)	25.29×10^{-11} (cm2/sec) (ml O2/ml x mm Hg)	28.91×10^{-11} (cm2/sec) (ml O2/ml x mm Hg)
Specific Gravity (wet) (g/cm^3)	1.086	1.113	1.088

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 5 2008

Clearlab SG Pte. Ltd.
c/o Martin Dalsing, Official Correspondent
Medvice Consulting, Inc.
806 Kimball Ave.
Grand Junction, CO 81501

Re: K080632
Trade/Device Name: Clear 1-Day Daily Disposable Soft Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lenses
Regulatory Class: Class II
Product Code: MVN, LPL
Dated: September 8, 2008
Received: September 12, 2008

Dear Mr. Dalsing:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Device Name: Clear1-day® (hioxifilcon A) Daily Disposable Soft Contact Lenses

INDICATIONS FOR USE:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Myra Smith

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K080632